K072993

1313 5th St. SE
Suite 205
Minneapolis, MN 55414
Ph: 612-455-0550
Fax: 612-455-0551

# 510(k) Summary

Company Name: AEIOMed, Inc.
1313 5th Street SE, Suite 205
Minneapolis, MN 55414

FEB 8

Contact: Gary Payment, Director of Quality Assurance

Phone: (612) 455-0564

Fax: (612) 455-0551

Summary Date: October 22, 2007

Trade Name: Reusable Headrest® with Nasal Seal

Common Name: CPAP Accessory: Nasal CPAP Mask

Classification Name: 21 CFR 868.5905, Non-Continuous (Respirator) Ventilator

Predicate Devices:

510(k) Number: K042130
Manufacture: AEIOMed, Inc.
Trade Name: CPAP Patient Interface

510(k) Number: K042403
Manufacture: ResMed Ltd.
Trade Name: Mirage Swift™

## 1.0 Description of Device

The Headrest® with Nasal Seal is an accessory to continuous positive airway pressure (CPAP) devices, which are applied to treat Obstructive Sleep Apnea with CPAP or Bi-Level CPAP. The Headrest® with Nasal Seal is initially used under the direct supervision of a trained medical professional. The Headrest® with Nasal Seal function and

applications are applied in a clinical or home setting when the patient is treated for obstructive sleep apnea by the application of CPAP therapy.

## 2.0 Intended Use

The Headrest® with Nasal Seal is a reusable accessory to continuous positive airway pressure (CPAP) devices, which are applied to treat Obstructive Sleep Apnea with CPAP or Bi-Level CPAP therapy.

## 3.0 Technology

The Headrest® with Nasal Seal has three significant components:

1) Headrest,
2) Nasal Seal, and
3) Tubing.

The Headrest holds the device Tubing and the Nasal Seal in place on the user's head. The Headrest is adjustable by the user. The Nasal Seal is made from a silicone material which connects to the Headrest. The Nasal Seal provides the airflow pathway to the user's nasal openings. The Tubing connects to the CPAP System. The Tubing and Headrest pass the constant air pressure of the CPAP System to the Nasal Seal. The Headrest allows the positioning of the Nasal Seal for the comfort of the user.

The Headrest and Nasal Seal are reusable components. The Tubing is single patient use.

Performance of the Headrest and Nasal Seal after 30 cleaning and disinfection exposures to Cidex® OPA indicated both components continued to meet specifications.

## 4.0 Conclusions

The reusable Headrest® with Nasal Seal is substantially equivalent to the predicate devices. Laboratory testing and guidance document compliance were provided to support the reusable Headrest® with Nasal Seal Instructions for Use for cleaning and disinfection; and performance after cleaning and disinfection. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

AEIOMed, Incorporated
C/O Mr. Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K072993
Trade/Device Name: Reusable CPAP Patient Interface
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: February 1, 2008
Received: February 4, 2008

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

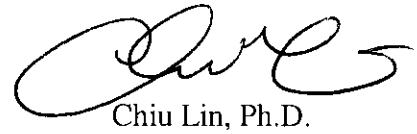
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072993

Device Name: Reusable CPAP Patient Interface

Indications for Use:

The Headrest® with Nasal Seal is a reusable accessory to continuous positive airway pressure (CPAP) devices, which are applied to treat Obstructive Sleep Apnea with CPAP or Bi-Level CPAP therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072993